

Meeting Minutes

AGENDA

DEPARTMENT OF HEALTH BOARD OF PHARMACY FULL BOARD MEETING

June 9-10, 2015

B Resort & Spa

1905 Hotel Plaza Blvd.

Lake Buena Vista, FL 32830

(407) 828-2828

PLEASE TURN OFF ALL CELL PHONES, PAGERS AND BEEPERS DURING THE MEETING. THANK YOU.

Board Members

Michele Weizer, PharmD, Chair, Boca Raton
Debra B. Glass, BPharm, Vice-Chair, Tallahassee
Win Adams, CSA, Consumer Member, Fern Park
Goar Alvarez, PharmD, Cooper City
Leo "Lee" Fallon, BPharm, PhD, The Villages
Gavin Meshad, Consumer Member, Sarasota
Jeenu Philip, BPharm, Jacksonville
Mark Mikhael, PharmD, Orlando
Jeffrey J. Mesaros, PharmD, JD, Orlando

Board Staff

Allison Dudley, Executive Director
Emily Roach, Program Operations Administrator
Amber Greene, Regulatory Specialist III

Board Counsel

David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

Department of Health Staff

Matthew Witters, Assistant General Counsel
Christopher Jurich, Assistant General Counsel

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the board's website.

Tuesday, June 9, 2015 - 9:00 a.m.

Meeting called to order by Dr. Weizer at 9:05 a.m.

All members were present.

TAB 1: REPORTS - Michele Weizer, PharmD, Chair**A. Chair's Report - Michele Weizer, PharmD**

Dr. Weizer discussed the PARE exam and explained it is offered through NABP. She also stated there is a sample exam on the NABP website.

Dr. Weizer reminded all the Board members about the upcoming District III meeting being held in St. Augustine in August.

B. Executive Director's Report - Allison Dudley, Executive Director**1. iViewer discussion**

Ms. Dudley stated that the updated iViewer is not available yet for testing, but hopes to

have something ready for the Board members to test at the August board meeting.

2. Update - *Are You Renewal Ready?* campaign

Ms. Dudley reminded the Board as well as the audience to make sure they have registered in CE Broker.

3. Enrolled Bills 2015 Legislative Session

A. HB 279

1. Rule 64B16-26.1031 and Rule 64B16-26.1032

Ms. Dudley explained to the Board that Rule 64B16-26.1031 allows an intern to administer vaccines and suggested the rule be opened for development.

Motion by: Dr. Mesaros, to open Rule 64B16-26.1031 and Rule 64B16-26.1032 for development. Motion carried.

2. Rule 64B16-26.1032

Ms. Dudley handed out a draft application for Immunization Administration Certification and requested the Board take a look and make any proposed changes. She then stated the application needs to be ready by July 1, 2015.

The Board members decided to take a look at the application and vote on Wednesday.

B. HB 751

Ms. Dudley explained that HB 751 meant a caregiver can get a prescription for an opioid antagonist.

C. HB 1049

No action by the Board at this time.

4. Proposed Memorandum of Understanding

Ms. Dudley explained the purpose of Proposed Memorandum of Understanding is to establish an agreement between the State of Florida and the U.S. Food and Drug

Administration (FDA) regarding the distribution of inordinate amounts of compounded human drug products interstate and the appropriate investigation by each specific state of complaints relating to compounded human drug products distributed outside such State. This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a), and does not apply to drugs that are compounded by registered outsourcing facilities.

Ms. Dudley stated the NABP is asking for comments; the MOU will be open for comments until June 19, 2015. Ms. Dudley advised Board members she can submit comments if they have a concern or choose to not comment. She then stated this is just a draft and States will have 90 days to sign. The number of states that have signed has not been released.

C. Attorney General's Report - David Flynn, Assistant Attorney General

1. Monthly Rules Report

Mr. Flynn went over current rules report.

Mr. Flynn requested the Board to discuss and determine if this proposed language belongs under 64B16-27.100. This section was moved from Rule 64B16-27.420 to Rule 64B16-27.100. The proposed language is as follows:

All registered pharmacy technicians shall identify themselves as registered pharmacy technicians by wearing a type of identification badge that is clearly visible which specifically identifies the employee by name and by status as "registered pharmacy technician". And all registered pharmacy technicians shall state their names and verbally indemnify themselves as registered pharmacy technicians in the context of telephone or other forms of communication.

Motion: by Dr. Mesaros, to accept proposed language with "technician" being added to language and placed in Rule 27.100. Motion carried.

Motion by: Dr. Weizer, not to effect small business; cost to not exceed \$200,000 in one year or \$1 million in five years. Motion carried.

2. Declaratory Statements

A. Centra Care- Review Draft Order

Representatives present were Cynthia Mikos, Esq., and Timothy Hendrix.

Mr. Flynn briefed the Board on the issues discussed at the April Board meeting when the Petition was first discussed. Mr. Flynn then went over the current drafted Final order.

Dr. Weizer asked how a prescription is offered to a patient.

Mr. Hendrix stated the patient is offered the prescription verbally, electronically or a by written prescription. Dr. Weizer asked Mr. Hendrix how someone could tell what method

the patient chose to fill their prescription. Mr. Hendrix advised the Board he could access the dispensing software or look at the medical record and it would show which method they chose. He then stated he verified which printer the prescription was printed from.

Mr. Flynn recommended to Ms. Mikos to withdraw current Petition for Declaratory Statement and make amendments to be more specific. Ms. Mikos asked to withdraw the petition.

Motion by: Dr. Mesaros, to approve request to withdraw Petition for Declaratory Statement and make amendments. Motion carried.

~~B. Prescription Health Network, LLC.~~ Continued to August

3. Petition for Temporary Waiver

A. Good Samaritan Medical Center, Inc.

Michael Glazer served as counsel for Good Samaritan Medical Center. Representatives present were Debra Taldi, Director of Pharmacy, and Kellee Bowers, Project Architect.

Mr. Glazer requested a continuance of the temporary waiver due to construction issues.

Mr. Bowers stated the construction should be complete by summer of 2016.

Motion by: Dr. Mikhael to approve request for Temporary Waiver. Motion carried.

D. Investigative Services Report - Michelle Miller, Field Operations Administrator

Ms. Miller stated out of 6,965 pharmacies, 6,619 have been inspected (95.03 %).

Ms. Miller stated out of 8,720 Dispensing Practitioners, 7,043 have been inspected (80.53 %).

Ms. Miller stated SSCP Inspections started with 553 and have completed 538 -- 15 remain to be inspected. All SSCP inspections that are able to be inspected will be inspected by end of the fiscal year.

Ms. Miller stated approximately 500 of the remaining dispensing practitioners are located out of state but wish to keep their modifier even though they are not dispensing in Florida.

TAB 2: BUSINESS - Michele Weizer, PharmD, Chair

A. Ratification of Issued Licenses/Certificates & Staffing Ratios

1. Pharmacist (Licensure)(Client 2201) - 133
2. Pharmacist (Exam Eligibility)(Client 2201) - 117
3. Pharmacist Interns (Client 2202) - 146
4. Registered Pharmacy Technicians (Client 2208) - 1,033
5. Consultant Pharmacist (Client 2203) - 42
6. Nuclear Pharmacist (Client 2204) - 0
7. Pharmacy/Facilities (Client 2205) - 146
8. Nonresident Sterile Compounding (Client 2210) - 54
9. CE Providers - 19
10. CE Courses - 37
11. CE Individual Request (Approved) - 4
12. CE Individual Request (Denied) - 0

Motion: by Dr. Fallon, to approve ratification of issued licenses. Motion carried.

B. Review and Approval of Minutes

1. April 6-8, 2015 Meeting Minutes

Motion: by Dr. Alvarez, to approve April meeting minutes. Motion carried.

Break: 10:35-10:57

C. VucaHealth Presentation

David Medvedeff, CEO, and Phil Burgess, consultant, were present. Representatives presented a power point presentation about MedsOnCue.

The representatives explained to the Board that MedsOnCue is an innovative digital patient education solution that reinforces safe medication use by providing patients with on-demand access to prescription-specific videos. The videos provided comprehensive information on prescribed medications; proper usage, expected benefits and side effects.

D. 2016 Calendar- Discussion on Dates and Meeting Locations

Ms. Dudley stated to the Board the proposed meeting dates for 2016 board meetings and advised if there are concerns we can address them. The Board discussed potential meeting dates for October due to holiday conflicts.

Motion by: Dr. Mesaros, to accept the provided calendar and select Oct. 18-19, as first preference for October meeting dates with Oct. 5-6 as backup dates. Motion carried.

Ms. Dudley advised the Board we need to select meeting locations for the 2016 Board meeting schedule.

The Board discussed the following locations for 2016: Tampa, Orlando, South Florida, Gainesville, Jacksonville or Tallahassee as well as Ft. Myers and Sarasota area. Selections were Gainesville, Tallahassee or Jacksonville, South Florida, Tampa or Sarasota, and

Orlando twice.

Motion: by Dr. Mesaros, to accept proposed locations as discussed. Motion carried.

E. CE - South Florida Society of Nuclear Medicine Technologists

Dr. Weizer advised the Board member that during the South Florida Society of Nuclear Medicine Technologists meeting last September the paperwork submitted to CE Broker was not submitted correctly. South Florida Society of Nuclear Medicine Technologists has requested their general CE be converted to nuclear CE. Dr. Weizer stated the Board office needs to modify the current application since this error has happened before.

Motion: by Dr. Mesaros, to approve request to change general CE into Nuclear CE and to modify the current design on application. Motion carried.

F. New Business

None at this time.

Dr. Weizer opened the floor for public comments.

None at this time.

Motion by: Dr. Mesaros to ADJOURN the meeting at 11:49 a.m. Motion Carried.

Wednesday, June 10, 2015 - 9:00 a.m.

Meeting called to order by Dr. Weizer at 9:04 a.m.

All members were present.

TAB 3: COMMITTEE REPORTS & ACTIONS (FROM 6/9) - Michele Weizer, PharmD, Chair

1. Compounding Committee- Michele Weizer, committee chair

Dr. Weizer asked the Board to open Rule 64B16-27.700 for development due to items in the rule conflicting with federal law and it needing to be more specific regarding veterinary products.

Motion by: Jeenu Phillip, to open Rule 64B16-27.700 for development. Motion carried

2. Controlled Substance Standards Committee- Michele Weizer, committee vice chair

Dr. Weizer asked the Board to open Rule 64B16-27.831 for development.

Motion by: Gavin Meshad to open Rule 64B16-.27.831 for development. Motion carried.

TAB 4: DISCIPLINARY CASES - Matthew Witters, Esq. & Michelle Weizer, PharmD, Chair

1. Prosecution Services Report - Matt Witters, Assistant General Counsel

Mr. Witters stated the inventory was 335 cases last time and is now down to 326 cases.

Mr. Witters stated we currently have 222 cases that are 1 year or older and asked the Board to consider allowing to continue to prosecute those cases.

Motion: by Debra Glass, to allow PSU to continue prosecuting cases one year and older. Motion carried.

SETTLEMENT AGREEMENTS - APPEARANCE REQUIRED

SA-1 Michael G. Kenney, R.Ph. Case No. 2013-19918

Respondent was present and sworn in. Respondent was not represented by counsel.

Dr. Fallon and Ms. Glass were recused due to participation on the probable cause panel.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: Count one: violation of Florida Statute 456.072(1)(q), FS (2013), by violating a lawful order of the department or board, failing to comply with a lawfully issued subpoena of the department; Count two: violation of Florida Statute 456.072(1)(hh), FS (2013), provides that being terminated from a treatment program for impaired practitioners, which is overseen by an impaired practitioner consultant as described in section 456.076 FS.

The terms of the Orally Amended Settlement Agreement were: Appearance; Fine \$1000.00 to be paid within 12 months of the Final Order; costs of \$1757.62 to be paid within 12 months of filing of Final Order; Evaluation- Contacting PRN and undergo evaluation by Department/PRN approved evaluator and follow all requirements and recommendations; Suspension until safe to practice with reasonable skill and safety and appearance before the Board; Probation- Upon conclusion of period of suspension the pharmacist license will be placed on two years' probation or for a period concurrent with PRN contract if any, during the period of probation Respondent shall not act as PDM at any Florida pharmacy and must follow all PRN recommendations and requirements.

Motion by: Dr. Mikhael to accept the orally amended Settlement Agreement. Motion carried.

SA-2 John T. Reading, R.Ph. Case No. 2012-16088

Respondent was not present. Respondent was not represented by counsel.

Dr. Mesaros and Ms. Glass were recused due to participation on the probable cause panel.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Florida Statute 456.072(1)(k) and section 465.016(1)(r), FS (2012) by violating Section 465.022(11)(a), FS by failing to ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

The terms of the Settlement Agreement are: Respondent shall place license in retirement status within seven days within the effective date of the Final Order; Respondent will not be able to reactivate his license from retirement status without petitioning the Board and appearing before the Board, and demonstrating he is competent to practice the profession of pharmacy.

Motion by: Dr. Mikhael, to waive appearance. Motion carried.

Motion by: Dr. Fallon, to accept the Settlement Agreement. Motion carried.

SA-3 Cedrick Chi Hang Wong, R. Ph. Case No. 2014-08310

Respondent was present and sworn in. Respondent was represented by attorney Brian Kahn.

Dr. Alvarez and Ms. Glass were recused due to participation on the probable cause panel.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Florida Statute 456.072(1)(k), FS (2013), by violating section 465.022(11)(a), FS (2013), by failing to ensure the permittee's compliance with Rule 64B16-27.420(4)(a), Florida Administrative Code and Rule 61N-1.012(1)(a), Florida Administrative Code.

The terms of the Settlement Agreement are: Appearance; Fine of \$1500 to be paid within 30 days of filing of Final Order; Costs of \$1384.40 to be paid within 1 year of filing of Final Order; Continuing Education- completion of Board-approved, 12-hour Laws and Rules course within 1 year of filing of Final Order; Probation- 1 year probation, during that time Respondent shall not serve as prescription department manager in a Florida pharmacy. Respondent has already completed the Laws and Rules continuing education requirement.

Motion by: Dr. Mikhael, to accept the Settlement Agreement. Motion carried.

SA-4 Alan E. Wingerter, R.Ph Case No. 2014-11272

Respondent was present and sworn in. Respondent was not represented by counsel.

Dr. Fallon and Dr. Alvarez were recused due to participation on the probable cause panel.

Jeenu Philip recused himself due to being a past supervisor of the respondent.

Mr. Jurich represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: Count one: violation of Florida Statute 456.072(1)(k), FS (2013), through a violation of section 465.022(11)(a), FS (2013), by failing to ensure the permittee's compliance with Rule 64B16-28.110, Florida Administrative Code. Count two: violation of Florida Statute 456.072(1)(k), FS (2013) by violating section 465.022(11)(a), FS, by violating section 499.007(1), FS (2013), which provides that a drug or device is misbranded if its labeling is in any way false or misleading.

The terms of the Amended Settlement Agreement are: Appearance; Fine \$2,000.00 to be paid within 30 days of filing of Final Order; Costs of \$720.65 to be paid within one year of filing of Final Order; Continuing Education- Completion of Board-approved 12-hour Laws and Rules course within 1 year of filing of Final Order; Probation- 1 year probation, during that time Respondent shall not serve as prescription department manager in a Florida pharmacy and must submit monthly reports where he is employed and who he is supervised by; Make mandatory appearance before the Board during last 3 months of probation.

Motion by: Dr. Mikhael, to accept the Amended Settlement Agreement. Motion carried.

SA-5 Shelly Hien Gelinas, R. Ph. Case No. 2014-10627

Respondent was present and sworn in. Respondent was represented by attorney Martin Dix.

Dr. Mikhael and Mr. Meshad were recused due to participation on the probable cause panel.

Mr. Jurich represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: Count one: violation of Florida Statute 465.016(1)(g), FS (2013), by furnishing upon prescription an ingredient or article different in any manner from the ingredient or article prescribed. Count two: violation of Florida Statute 456.072(1)(k), FS (2013), through violation of section 465.016(1)(t)2, FS (2013), by committing error or omission during the performance of a specific function of prescription drug processing, which includes, for purposes of this paragraph, entering prescription data in the pharmacy's record.

The terms of the Orally Amended Settlement Agreement were: Appearance; Fine \$500.00 to be paid within 30 days of filing of Final Order; Costs of \$908.84 to be paid within 90 days of filing of Final Order; Continuing Education- Completion of Board approved 8 hour Medical Errors course within 1 year of filing of Final Order.

Motion by: Jeenu Philip, to accept the Orally Amended Settlement Agreement. Motion carried.

SA-6 Germaine Pharmacy & Compounding Inc. Case No. 2014-19179

Respondent was represented by owner Mieba Constance Chukwueke, R.Ph., who was sworn in. Respondent was not represented by counsel.

Dr. Mikhael was Chair.

Dr. Weizer and Ms. Glass were recused due to participation on the probable cause panel.

Mr. Jurich represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Florida Statute 465.023(1)(c), FS (2014), by and through violating of Rule 64B16-27.797(1)(a), Florida Administrative Code, which provides that all sterile compounding shall be performed in accordance with the minimum practice and quality standards of the following chapters of the United States Pharmacopeia ("USP"): Chapter 797, Pharmaceutical Compounding- Sterile Preparations.

The terms of the Settlement Agreement were: Appearance; Fine \$3,000.00 to be paid within 30 days of filing of Final Order; Costs of \$986.14 to be paid within 90 days of filing of Final Order; Probation- One year probation with semi-annual inspections at the Respondent's cost, submit corrective action plan to Board within 90 days, mandatory appearance before the Board in the last 3 months of probation; Correct all alleged deficiencies.

Motion by: Dr. Alvarez, to accept the Settlement Agreement. Motion carried.

SA-7 Mieba Constance Chukwueke, R. Ph. Case No. 2014-19253

Respondent was present and sworn in. Respondent was not represented by counsel.

Dr. Mikhael was Chair.

Dr. Weizer and Ms. Glass were recused due to participation on the probable cause panel.

Mr. Jurich represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Florida Statute 456.072(1)(k), FS (2014), by and through violating of section 465.022(11)(a), FS (2014), by failing to ensure the permittee's compliance with Rule 64B16-27.797(1)(a), Florida Administrative Code, which

provides that all sterile compounding shall be performed in accordance with the minimum practice and quality standards of the following chapters of the United States Pharmacopeia (“USP”): Chapter 797, Pharmaceutical Compounding -Sterile Preparations.

The terms of the Orally Amended Settlement Agreement were: Appearance; Costs of \$764.32 payable within 90 days of filing of Final Order; Continuing Education- Completion of Board-approved 12-hour Laws and Rules and Critical Point Sterile Compounding Boot Camp to be completed within 1 year of filing of Final Order; 1 year restriction limited to only serve PDM at Germaine Pharmacy.

Motion by: Dr. Fallon, to accept the Orally Amended Settlement Agreement. Motion carried.

~~SA-8 Michael Paul Fulghum, R. Ph. Case No. 2014-17625~~ *Continued to August Board Meeting*

SA-9 Madhavi Chowdary Balineni, R.Ph, Case No.
2014-03209 (Alvarez/Glass)

Respondent was present and sworn in. Respondent was not represented by counsel.

Dr. Alvarez and Ms. Glass were recused due to participation on the probable cause panel.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Florida Statute 465.016(1)(g), FS (2013), by using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any matter from the ingredient or article prescribed.

The terms of the Settlement Agreement are: An appearance in front the Board; a fine of \$500.00 to be paid within 30 days of filing of Final Order; costs of \$2,010.64 to be paid within 90 days of filing of Final Order; complete a Board approved 8-hour prevention of medical errors continuing education course with in 1 year of the filing of Final Order.

Motion by: Dr. Mikhael, to accept the Settlement Agreement. Motion carried.

SA-10 Precision Pharmacy Case No. 2014-02868
(Weizer/Glass)

Respondent was present and sworn in. Respondent was represented by attorney Ann Marchant.

Representatives present were Compliance Officer Rachel Taggs and Pharmacist-in-Charge Shauna Dougherty.

Dr. Mikhael was Chair.

Dr. Weizer and Ms. Glass were recused due to participation on the probable cause panel.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Florida Statute 456.072(1)(f), FS (2013), by having a license or the authority to practice any regulated profession revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of any jurisdiction, including agencies or subdivisions, for a violation that would constitute a violation under Florida law. The licensing authority's acceptance of a relinquishment of licensure, stipulation, consent order, or other settlement, offered in response to or in anticipation of the filing of charges against the license, shall be construed as action against the license.

The terms of the Settlement Agreement are: An appearance in front the Board; a fine of \$5,000.00 to be paid within 90 days of filing of Final Order; costs of \$1223.13 to be paid within 90 days of filing of Final Order; Probation- Two years' probation; Refrain from shipping compounded sterile products into the state of Florida until Board issues a Non-Resident Sterile Compounding Permit.

Motion by: Dr. Fallon, to accept the Settlement Agreement. Motion carried.

(Break from 10:44 to 11:30 a.m.)

Board did Tab 5 C. 6 Physician Preferred, and returned to Tab 4 SA-4 Alan E. Wingerter, before proceeding to Determination of Waivers. Minutes reflect actions in order of agenda.

DETERMINATION OF WAIVERS

DOW-1 Edy Payoute, R. Ph. Case No. 2014-05414

(Fallon and Alvarez)

Respondent was present and sworn in. Respondent was not represented by counsel

Dr. Alvarez and Mr. Fallon were recused due to participation on the probable cause panel.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Section 456.072 (1)(k), FS (2013), through a violation of section 465.022(11)(a), FS (2013), by failing to ensure the permittee's compliance Rule 64B16-27.420(4)(a), Florida Administrative Code, Rule B16-27.300 (3)(a)(2), Florida Administrative Code, Rule 64B16-28.140(4)(h)(i), Florida Administrative Code, Rule 64B16-27.700(3)(d), Rule 64B16-27.100(1)(4), Florida Administrative Code and Rule 64B16-28.1081, Florida Administrative Code adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

Motion by: Dr. Mikhael, to find that respondent was properly served and had requested a formal hearing. Motion carried.

Motion by: Ms. Glass, to accept the investigative report into evidence for the purposes of

imposing a penalty. Motion carried.

Motion: by Ms. Glass, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Dr. Mikhael, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Recommended Penalty: \$2,000 fine payable within 90 days; Costs of \$704.71 payable within 90 days; Restriction that Mr. Payoute can't serve as PDM for 1 year.

Motion: by Mr. Meshad, to accept the recommendations of the Department. Motion carried.

Motion by: Debra Glass, to move costs of \$704.71. Motion carried.

DOW-2 Charles Douglas Bayne II, RPT case No. 2013-17787
(Glass and Weizer)

Respondent was not present. Respondent was not represented by counsel

Dr. Weizer and Ms. Glass were recused due to participation on the probable cause panel.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Section 456.072(aa), FS (2013), by testing positive for any drug, as defined in s. 112.0455, on any confirmed pre-employment or employee ordered drug screening when the practitioner does not have a lawful prescription and legitimate medical reason for using the drug.

Motion by: Dr. Alvarez, to find that respondent was properly served and had requested a formal hearing. Motion carried.

Motion by: Dr. Alvarez, to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Dr. Alvarez, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Dr. Alvarez, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Recommended Penalty: Costs of \$1,055.72; Suspension until PRN evaluation and deemed safe to practice with reasonable skill and safety.

Motion by: Mr. Phillip, to accept the recommendations of the Department. Motion carried

DOW-3 Julie A. Smith, R. Ph. Case No. 2012-08353
(Mullins and Risch)

Respondent was not present. Respondent was not represented by counsel

Mr. Jurich represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Section 456.072(1)(c), FS (2012), by being convicted of found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or ability to practice, a licensee's profession.

Motion by: Ms. Glass, to find that respondent was properly served and had requested a formal hearing. Motion carried.

Motion by: Ms. Glass, to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Ms. Glass, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Ms. Glass, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Recommended Penalty: Revocation.

Motion by: Ms. Glass, to accept the recommendations of the Department. Motion carried.

PSU withdrew motion to assess cost.

DOW-4 Parkdale Pharmaceuticals Corp.
Case No. 2014-05390
(Fallon and Alvarez)

Respondent was represented by owner Roberto Facey, who was sworn in. Respondent was not initially represented by counsel. This case was continued until after lunch, and Attorney Martin Dix represented Mr. Facey.

Dr. Fallon and Dr. Alvarez were recused due to participation on the probable cause panel.

Mr. Jurich represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: Count one: violation of Section 456.072(1)(k), FS (2013,2014), through a violation of section 465.023(1)(c), FS (2013,2014), by violating Rule 64B16-28.140(4)(b)(f)(h)(i), Florida Administrative Code. Count two: violation of Section 456.072(1)(k), FS (2013,2014), through a violation of section 465.023(1)(c), FS (2013,2014), by violating section 499.007(1), FS (2013,2014), which provides that a drug or device is misbranded if it's labeling is in anyway false or misleading.

Motion by: Ms. Glass, to find that respondent was properly served and had requested a formal hearing. Motion carried.

Motion by: Ms. Glass, to accept the investigative report into evidence for the

purposes of imposing a penalty. Motion carried.

Motion: by Ms. Glass, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Ms. Glass, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Recommended Penalty: \$2,000 fine; costs of \$866.16 payable in 90 days; 1 year probation; semi-annual inspections at the respondent's cost; 12-hour Board-approved Laws and Rules course; corrective action plan submitted to Board within 90 days; re-appearance before the Board during last three months of probation; no compounding until pharmacy has passed an inspection performed by a State inspector. (Board Chair will approve inspection).

Respondent requested a continuance due to the fact he misunderstood what the alleged violations were.

Motion by: Dr. Mikhael, to deny request for continuance. Motion carried.

Dr. Mikhael questioned Mr. Facey about the pharmacy's business.

[Mr. Martin Dix offered to advise Mr. Facey and the case was continued until later in the afternoon.]

Mr. Dix said the respondent agreed to the facts. He said Mr. Facey plans to bring in a staffing agency to assist the pharmacy with coming into compliance with all pharmacy laws and compounding laws.

Motion by: Dr. Mikhael, to accept the recommendations of the Department. Motion carried.

DOW-5 Priscilla Torres, RPT Case No. 2014-15153
(Fallon and Alvarez)

Respondent was not present. Respondent was not represented by counsel

Dr. Fallon and Dr. Alvarez were recused due to participation on the probable cause panel.

Mr. Witters represented the Department and presented the case to the Board.
Allegations of the Administrative Complaint: violation of Section 456.016(1)(e),

Chapter 893.13(6)(a) FS (2013,2014) Chapter 593.13(7)(a)(9) FS (2013,2014).

Motion by: Ms. Glass, to find that respondent was properly served and requested a formal hearing. Motion carried.

Motion by: Ms. Glass, to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Ms. Glass, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Ms. Glass, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Recommended Penalty: Revocation

Motion by: Ms. Glass, to accept the recommendations of the Department. Motion carried.

PSU withdrew motion to assess cost.

VOLUNTARY RELINQUISHMENTS

VRs voted on at one time: VR-2, VR-3 and VR-4 . (PCP waived)

Motion: by Ms. Glass, to accept the above-listed Voluntary Relinquishments as a group. Motion carried.

VR-1 Carlos Manuel Perez, RPT Case No. 2014-07596
(Weizer and Philip)

Debra Glass served as Chair.

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

Motion: by Dr. Fallon, to accept Voluntary Relinquishments. Motion carried.

VR-2 Miracle Pharmacy & Discount Inc. Case No. 2014-18671
(PCP Waived)

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

Accepted via group motion.

VR-3 DNA Pharmacy Inc. Case No 2015-03748
(PCP Waived)

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

Accepted via group motion.

VR-4 Leslie Carol Morehouse, RPT Case No. 2015-06812
(PCP Waived)

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

Accepted via group motion.

VR-5 Regenax Pharmaceuticals Inc. Case No. 2013-13295
(Mikhael and Meshad)

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

Motion: by Dr. Fallon, to accept Voluntary Relinquishments. Motion carried.

VR-6 Karen M. Dunlap, R.Ph. Case No. 2014-17025
(Mesaros and Glass)

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

Motion: by Dr. Fallon, to accept Voluntary Relinquishments. Motion carried.

VR-7 William Clero, R.P.T. Case No. 2013-05745
(Weizer and Meshad)

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

Motion: by Dr. Fallon, to accept Voluntary Relinquishments. Motion carried.

INFORMALS

I-1 ~~Treshena L. Dixon, R.Ph., C. Ph., Case No. 2011-17089-~~
~~and 2011-17091-MDT~~ Continued to August Meeting

TAB 6: APPLICATIONS REQUIRING BOARD REVIEW- **Debra Glass, BPharm, Vice-Chair**

A. Pharmacist Applications

1. Shajaun Devoir Harrison, File: 61291

Respondent was present and sworn in. Respondent was not represented by counsel.

Mr. Harrison presented the Board with a recommendation letter from current employer LMC Medical Supply. Ms. Dudley read the letter out loud for the Board members and audience.

David Flynn stated the Board could not issue a license due to the end date of his probation from his 2002 arrest. Applicants must wait 15 years from the end date of the probation, not the arrest date.

Ms. Glass suggested he withdraw his current application. Mr. Harrison requested to withdraw his application.

Motion: by Dr. Weizer, to approve Mr. Harrison's request to withdraw his application. Motion carried.

2. John Major, File: 43928

Respondent was present and sworn in. Respondent was represented by Attorney

Martin Dix.

Mr. Dix requested Mr. Major be issued a restricted license, not a full license to where he would work as a pharmacist in a facility that did not have medicinal drugs.

Dr. Penny Ziegler with PRN stated he is currently in compliance with PRN since the letter submitted to the Board office last week. Mr. Major has recently been diagnosed with a new disease. Mr. Major's psychiatrist and Dr. Ziegler both feel Mr. Major would need to be reevaluated in 6 months to see how the new medication is working. Dr. Ziegler stated more time is needed before he can be deemed safe to practice. Dr. Ziegler stated she would support the Board's decision to issue a limited license.

Ms. Glass asked Mr. Dix if Mr. Major is looking to go and work in a call center environment. Dr. Ziegler stated that PRN generally wants participants in PRN to return to work in that type of environment with no drugs and see how the patient's stress levels are with returning to a work setting.

Mr. Major stated he's interested in working at a research center where he would be doing risk management and drug safety. He would not be working with drugs.

Mr. Flynn stated the Board could not issue a limited license but a license with restrictions. Dr. Alvarez stated he would feel more comfortable for the license to state what he's allowed to do versus what not allowed to do. Ms. Dudley stated if the Board issues a license with restrictions it would state that on the DOH website.

Motion: by Dr. Mikhael, to grant license with the following conditions and restrictions:

Mr. Major must comply with all terms of PRN contract; license will be restricted so he will not have access to medicinal drugs such as controlled or legend drugs; before any access to medicinal drugs he must reappear before the Board and with the support of PRN demonstrate safe to practice with reasonable skill and safety; upon the lifting of restrictions the Board shall reserve jurisdiction to impose up to 5-year probation, at that time any terms would be related to basis of restricted license; if employed during restriction he must provide a copy of the Final Order granting restricted license to employer or to any potential employers. Motion carried.

3. Michael Jiordano, File: 60976

Respondent was present and sworn in. Respondent was not represented by counsel.

Motion: by Ms. Glass, to approve the application. Motion carried.

4. Michael Saavedra, File: 46519

Respondent was not present. Respondent was not represented by counsel.

Motion: by Dr. Mikhael, to require an appearance at one of the next two Board meetings or application will be denied. Motion carried.

B. Pharmacist Intern Applications.

1. Andrea Economy, File: 20817

Respondent was present and sworn in. Respondent was not represented by counsel.

Motion: by Dr. Mikhael, to approve the application and require a PRN evaluation to be done within 60 days and comply with PRN terms. Motion carried.

2. Prince Tamaklo, File: 57112

Respondent was not present. Respondent was not represented by counsel.

Motion: by Dr. Mikhael, to deny application due to not meeting requirements. Motion carried

C. Pharmacy Permit Applications

1. California Pharmacy & Compounding Center, File: 53

Respondent was present and was sworn in. Respondent was not represented by counsel.

Representative present was Glenn Olsheim, Chief Operating Officer.

California Pharmacy and Compounding currently has pending discipline in California. The pending discipline is currently still in the accusation stage. The accusations are related to violations found in the FDA inspection report.

Mr. Olsheim advised the Board that California Pharmacy has had no recalls, complaints, warning letters nor have they failed a sterility test.

Mr. Flynn stated the Board would need an inspection report showing CGMP compliance.

Dr. Weizer recommended requesting a continuance.

Mr. Olsheim requested a continuance to provide documentation showing cGMP compliant and 483 responses.

Motion: by Dr. Mesaros, to approve the request for a continuance. Motion carried.

2. BET Pharm, LLC, File: 63

Respondent was present and sworn in. Respondent was not represented by counsel.

Representative present was Seth DePasquale, Pharmacist in Charge.

Mr. DePasquale stated there are many SOP and procedural changes that need to be made. He then stated he has made a lot of changes over the last 6 months.

Dr. Weizer stated her biggest concern is the Kentucky inspection form is not a 797-compliant inspection form and BET needed to be 100 percent compliant. Dr. Weizer recommended requesting a continuance.

Mr. DePasquale requested a continuance.

Motion: by Mr. Meshad, to approve request for continuance. Motion carried.

3. Pavilion Compounding Pharmacy, LLC. File: 136

Respondent was present and sworn in. Respondent was not represented by counsel.

Representative present was Kathy Crowley, part owner.

Dr. Weizer noted on the application there were numerous issues indicated on the George inspection report which were improper purchasing of compounding products, technicians compounding without supervision and unlicensed technicians. Mr. Flynn stated the Board would need a current report from the Georgia agency stating 797-compliant and suggested requesting a continuance.

Ms. Crowley requested a continuance.

Motion: by Dr. Mesaros, to approve request for a continuance. Motion carried.

4. Cantrell Drug Company, File: 24

Respondent was present and sworn in. Respondent was not represented by counsel.

Representative present was Robert Hutts, Pharmacist in Charge.

Cantrell Drug Company was required at the April Board meeting to provide its current policy and procedure manual.

Cantrell had provided the Board with current policy and procedures and answered questions.

Motion: by Dr. Mikhael, to approve the application and grant permit. Motion carried.

5. Unique Pharmaceuticals, File: 209

Respondent was present and sworn in. Respondent was not represented by counsel.

Representative present was JB Allinson.

David Flynn asked Mr. Allinson if the policy and procedures were still in draft stage. Mr. Allinson stated all policy and procedures are in draft stage at some point.

Dr. Weizer was concerned with the FDA inspection report missing data and sterility concerns within the pharmacy, the pharmacy policy and procedures manual and environmental monitoring.

Mr. Allinson stated he will send response from FDA and RC certification as requested by Dr. Weizer. He provided that information to the Board later in the meeting. Dr. Weizer reviewed the responses and certification and advised the Board that the requested documentation was provided, including a confidential copy of procedures and the FDA response.

Motion: by Dr. Mikhael, to approve the application. Motion carried.

6. Physician Preferred Medical, LLC. File: 117

Respondent was present and sworn in. Respondent was represented by Attorney Ed Bayo.

Representative present was Sean Riney.

Physician Preferred Medical was required by the Board at its April meeting to appear at the June meeting.

Motion: by Dr. Mikhael, to approve the application. Motion carried.

7. Precision Pharmacies, LLC. File: 131

Respondent was present and sworn in. Respondent was represented by Attorney Ann

Marchant.

Representatives present were Compliance Officer Rachel Taggs and Pharmacist-in-Charge Shauna Dougherty.

Ms. Marchant stated that the 2009 disciplinary case which was mentioned in the settlement agreement case earlier has been resolved.

Ms. Taggs stated Precision Pharmacies is currently licensed in 38 states and they are a veterinary pharmacy.

The compliance officer, Rachel Taggs proved detailed knowledgeable in the Florida statutes and office use procedure for Florida.

Motion: by Dr. Mikhael, to approve the application. Motion carried.

TAB 7: LICENSURE ISSUES

A. Request for Payment Extension

1. Richard Alonso

Respondent was present and sworn in by the court reporter. Respondent was not represented by counsel.

Dr. Raymond Pomm was present.

David Flynn stated we currently have 3 petitions for Mr. Alonso: a request for payment extension, a request for reinstatement of his license in case 2013-17661 and a request for modification to the final order entered in case 2012-06981. Mr. Alonso requested to defer payments until working again.

Mr. Pomm stated he was present to advocate for reinstatement. Ms. Dudley asked Dr. Pomm if Mr. Alonso violated the contract would he report it to the Board. Dr. Pomm advised the Board he would report any violations of the contract.

Motion: by Ms. Glass, to terminate suspension. Motion carried.

Motion: by Dr. Weizer, to accept request for payment extension. Mr. Alonso will be required to pay off fines before appearing before the Board to petition for termination of probation or it will be a violation of Final Order. Motion carried.

2. Joshua Wright

Respondent was not present. Respondent was not represented by counsel.

Mr. Wright has requested an extension to pay \$150 month until paid off.

Dr. Ziegler stated Mr. Wright has completed his requirements with PRN and is no longer under contract.

Motion: by Mr. Phillip to accept request for payment extension. Motion carried.

B. Petition for Termination of Probation

1. Biosic-Winzeler, Inc., Case No. 2013-15420

Respondent was present and sworn in by the court reporter. Respondent was not represented by counsel.

Motion: by Dr. Mesaros, to accept termination of probation upon acceptance of a successful inspection report. Motion carried.

2. David S. Blazy, Case No. 2008-14681

Respondent was present and sworn in by the court reporter. Respondent was not represented by counsel.

Dr. Ziegler with PRN stated Mr. Blazy has been fully compliant with PRN and is deemed safe to practice with reasonable skill and safety.

Motion: by Mr. Phillip, to accept request for termination of probation. Motion carried.

3. Edy Payoute, Case No. 2011-20031 (Related to DOW-1)

Respondent was present and sworn in by the court reporter. Respondent was represented by.

Mr. Flynn stated the case heard earlier in the day, (Case No.2011-20031) did not violate this probation.

Motion: by Mr. Meshad, to accept termination of probation. Motion carried.

Dr. Weizer opened the floor to public comments.

None at this time.

Motion: by Dr. Fallon to ADJOURN the meeting at 5:13 p.m. Motion carried.